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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,010	01/03/2001	Mark E. Dillon	E-1950	3438

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John F. A. Earley III  
86 The Commons At Valley Forge East  
1288 Valley Forge Road  
P.O. Box 750  
Valley Forge, PA 19482-0750

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/754,010

Applicant(s)

DILLON, MARK E.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11/29/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of Extension of Time and Amendment C received on November 29, 2002 are acknowledged. Claims 18-27 and 29-33 are included in the prosecution of this application. Claim 28 is cancelled.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 18-27 and 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Independent claims recite a first surface, second surface, and two different wound contacting surfaces. It is unclear if the first/second surfaces are the same as the wound contacting surfaces. Further, it is unclear what is meant by two different wound-contacting surfaces and their placements in regard to each other.

#### ***Claim Rejections - 35 USC § 103***

**Claims 18-27 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al (5258421) by itself or in view of Delmore et al (5939339).**

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate such as silicone-polytetrafluoroethylene IPN membrane. The reference teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps

moisture in and excess exudate is absorbed (col.5, lines50-68). Further, the gel layer is used as the adhesive and as an absorbent layer. The backing substrate is also useful as a burn blanket (col. 5, lines 30-33 and col. 6, lines 28-30). Additionally, the backing substrate may be covered by a silicone-coated release-liner (col. 6, lines 1-3).

Lorenz et al do not teach a specific example or the use of a pigmented substrate.

Delmore et al discloses a wound dressing that is porous, self-adhering, and capable of absorbing wound exudates (Note abstract). The dressing is made of an adhesive layer and an absorbent layer (example 2 and claim 1). Further, the reference teaches a pigmented adhesive layer (example 11).

Although Lorenz et al does not provide a specific example, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to use the tacky gel in combination with the IPN membrane as suggested by Lorenz et al. One would be motivated to do so since Lorenz teaches that the instant IPN layer keeps moisture in while absorbing wound exudates through the porous network while the polyurethane layer acts as the adhesive, absorbent layer. If it is desirous for one to make a distinction between layers, one of ordinary skill in the art would look to Delmore who teaches a pigmented substrate.

### ***Response to Arguments***

Applicant argues that teaches a wound dressing material wherein the gel is used to adhere to the skin and the substrate of an IPN of silicone-polytetrafluoroethylene is used as a outer layer. It is noted that applicant does not include arguments regarding Delmore et al (US '339).

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the amendment "as to provide disparate wound healing characteristics depending on which surface the dressing is placed in contact with the wound" is a functional limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In terms of the functional limitation, the examiner points out that the independent claims only require two different surfaces and since Lorenz et al (US '421) teaches two different surfaces, the prior art is capable of performing instant invention's functional limitation. Secondly, the examiner points out that the second layer taught by '421 is instant IPN of silicone-polytetrafluoroethylene; therefore it is the examiner's position that Lorenz's article is capable of performing said function. For a product claim, new use for the prior art product does not make it patentable since the product is the same and is capable of performing intended use.

In regards to the composite article, the claim requires two surface with disparate characteristics for wound healing. Webster's defines disparate as "markedly distinct in quality or character." Therefore, Lorenz et al (US '421) reads on instant claims. Firstly, US '421 teaches a wound dressing having a PVP/polyurethane gel that serves as an adhesive, for hydrating purposes (col. 5, line 10), and to absorb excess exudates (col.

5, lines 64-65). The substrate, which is made of different material, is taught to have another type of wound healing characteristic. The substrate prevents bacteria from entering the wound; therefore the substrate not only is different in physical characteristics but also in its functional characteristics.

***Claim Rejections - 35 USC § 102***

**Claims 18-20, 22-25, 28-29 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al (5147338).**

Lang et al teach a wound dressing containing a foam layer (polyurethane), a conformable film layer, and silicone coated release liner. The reference teaches a layer containing apertures. (Note examples 22-25).

***Response to Arguments***

Applicant argues that Lang does not teach a dressing with two different wound-contacting surfaces depending on which face the orientation of the dressing.

Applicant's arguments have been fully considered but they are not persuasive. As discussed above, the amendment "so as to provide..." is a functional limitation, which does not hold patentable weight. The examiner points out that the applicant is claiming a method of use in a product claim. Lang teaches two surfaces, which meets the requirement of the claims. Secondly, Lang teaches the conformable layer is an apertured layer having discrete raised areas and recesses (Note figures); therefore the layer will have different wound contacting points and reads on "different wound contacting surfaces" since there is not a uniform contact between the wound and the dressing.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

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*[Handwritten signature]*

February 12, 2003

*[Handwritten signature]*  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER